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Tuesday, 23 September 2014

Novel Neurotechnologies: Intervening on the Brain

By [Graeme Laurie](#)

The Nuffield Council on Bioethics has produced its latest report on the ethical, legal and social implications of novel neurotechnologies. This report is very timely because many of the technologies in question are on the cusp of moving from the research stage to the health context. They are important for a range of patients suffering from neurological conditions such as Parkinson's Disease, Alzheimer's, stroke, depression and OCD. Over 800,000 people suffer from dementia in the UK and 1 in 500 people have Parkinson's Disease.

The Nuffield Council Working Party which produced the report, and which included involvement from MI's Director, Graeme Laurie, seeks to strike a balance between the necessary caution required whenever science intervenes on the brain and the imperative to improve innovation, access and effective regulation of these technologies to help to ensure that the right treatments get to the right patients at the right time.

The technologies in question include:

- Deep Brain Stimulation (DBS): this is an invasive procedure requiring brain surgery to insert electrodes in specific regions of the brain in order to receive pulses of electric current from generators also inserted in the body (usually the chest). There is good evidence that DBS has helped thousands of patients suffering from Parkinson's by reducing the tremors associated with the condition. However, there is a cost, including sleep disruption and increased anxiety for some patients. The Nuffield Report argues that we must learn from the experiences of patients who have used DBS to date to see whether and how it might be used for other conditions that include Alzheimer's and even anorexia. We simply do not know enough at the moment about how these interventions work in practice. Accordingly, the Council recommends the establishment of publicly-available registers to capture and share patient and clinician experiences. It also recommends that patients being offered invasive procedures should receive independent counselling before they take part and this should include full information about likely benefits and risks.
- Brain-Computer Interfaces (BCIs): these technologies involve the placing of electrodes on the scalp (or occasionally in the brain) to record brain signals that can be translated to instructions that could allow patients to move artificial limbs or communicate better after a stroke. These technologies are still at the research stage but they have been picked up in some non-health contexts such as gaming and educational enhancement by companies suggesting that they can assist with learning and play. The problem is that we simply do not know enough about whether these devices work at all. The Council calls on the European Commission to regulate all non-therapeutic brain devices as if they were medical devices. This would allow proper oversight of market approval in the UK by the MHRA and would include capture of people's experiences of using them in European health databases. The Council further recommends parents and teachers should received official advice on the effectiveness – or not – of devices that claim to enhance children's learning.
- Neural Stem Cells: these very new methods involve the surgical injection of stem cells into parts of patients brains in an attempt to replace or regenerate brain

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tissue. Only one study is currently being trialed in the UK. Early results are, however, promising. Safety is clearly paramount in this and all other cases involving these technologies. For stem cells, however, the real challenge is to smooth the regulatory pathway from research to bedside. These technologies are regulated in the same way as pharmaceuticals and in that context it can cost over \$500 million dollars to get drugs to market. We do not currently know the costs of neural stem cell technologies but the regulatory system must do two things: (i) make research subject safety the top priority *while also* (ii) encouraging innovation in the field. The Nuffield Council welcomes recent initiatives between regulators both to work more closely together and to maintain effective dialogue with stem cell developers. More imaginative thinking is required to incentivise investors to commit to these developments without diluting effective scrutiny and patient safety.

The report is also concerned with excessive 'hype' around these new technologies. Headlines like 'Paralysed man's mind is "read"' are not only seriously inaccurate, but can also give rise to unnecessary fears or misinformation for patients deciding on whether novel neurotechnologies are for them. Accordingly, the Nuffield Council calls upon the media, press offices, research institutes, researchers and their funders to be more responsible in their communication about the reality and the limits of these technologies and offers clear guidelines on what responsible communication might look like. The overarching theme of this report is one of balance: there is considerable unmet need out there and we must proceed with caution. Equally, we required smarter regulation mechanisms that deliver both safety protection and effective treatments to the patient's who need them.

Link to report: <http://www.nuffieldbioethics.org/neurotechnology>

This post was first published on 25 June 2013.

Posted by **Mason Institute** at **08:51**



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